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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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GOODWIN PROCTER L.L.P.
7 BECKER FARM ROAD
ROSELAND, NJ 07068

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/641,104

Applicant(s)

BIRCHMEIER ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 8/21/03. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 39-43.

Claim(s) withdrawn from consideration: 9-19 and 29-38.

8. ☒ The proposed drawing correction filed on 21 August 2003 is a) ☐ approved or b) ☒ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: See Continuation Sheet

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues regarding first and second paragraphs, it also raise new issues regarding the mutants of the protein of beta-catenin, where the protein of beta-catenin and the mutation are not specified. In the amendment of July 21, 2003, the specification including Figs. 1-9 and Tables 1-4 have been amended, claims 39-41 have been amended, and claims 42 and 43 have been cancelled. Applicants' response has been fully considered, however, Fig. 3 and Table 4 are objected to, and claims 39-41 are rejected under 35 USC 112, first and second paragraphs.

If applicants' amendment were entered, it would have the following response:

1. The newly submitted Fig. 3 is objected to because the drawing cites "Peptid 35-56" and "Peptid 10-34", "Peptide 35-56" and "Peptide 10-34" should be used.
2. Table 4 is objected to because German are cited in the table.
3. Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide from armadillo domains of beta-catenin (arms 3-9; SEQ ID NOs: 6, 7, 8, 9, 10, 11 and 12) or specific mutants of these armadillo peptides of beta-catenin (arms 3-8) having residue 383, 469, 470, 386, 253, 274, or 338 being substituted by Ala, which inhibit the interaction between beta-catenin and LEF-1/TCF-4 (transcription factor), or between beta-catenin and APC or conductin (tumor suppressor protein), does not reasonably provide enablement for a mutant of beta-catenin protein which have mutation at position of residue 383, 469, 470, 386, 253, 274, or 338, where the peptide sequence of beta-catenin protein and the mutation at the specific position are not defined. The specification indicates some basic (Lys, Arg, His) or some aromatic amino acids in the armadillo repeat units 3-9 of beta-catenin can be mutated to Ala (pages 6-7; Fig. 5), and several critical amino acid residues of beta-catenin peptide which inhibit the interaction with LEF-1/TCF, APC, conductin or E-cadherin are identified (Figs 5 and 6; Table 2; pages 9-10). However, the specification fails to identify any other mutants besides the Ala substituents at specific positions of armadillo peptides of beta-catenin (arms 3-9). Moreover, the specification has not shown any other mutants having different amino acid sequences of beta-catenin protein than armadillo peptides of beta-catenin can inhibit the interaction between beta-catenin and a transcription factor or a tumor suppressor gene product. There are no working examples indicating various mutants of beta-catenin protein can affect the interaction between beta-catenin and a transcription factor or a tumor suppressor gene product. Furthermore, the specification does not provide any specific guidance on identities of mutants of various beta-catenin proteins other than the armadillo peptides of beta-catenin. Since the specification fails to provide sufficient guidance on the mutants of beta-catenin proteins, it is necessary to carry out further experimentation to assess the effects of various mutants of beta-catenin protein. In response, applicants indicate claim 39 has been amended to incorporate claims 42 and 43 to better defining the variants regarding the mutants (page 13 of the response). The response has been fully considered, however, the argument is found persuasive because the claim recites "the mutants of the protein of beta-catenin", where the peptide sequence of beta-catenin protein is not specified, although the position of mutation has been identified, the mutation at the specific position is also not defined, thus, it is not known which beta-catenin peptide is mutated and what peptide sequence the mutant has.
4. Claims 39-41 are rejected under 35 USC 112, second paragraph because the claim recites specific amino acid position(s) (e.g., His 470) without reference to an amino acid sequence identified with "SEQ ID NO:". It is not clear which amino acid sequence has His 470 being mutated. Claims 40 and 41 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend. In response, applicants indicate claims 42 and 43 have been cancelled (pages 13-14 of the response). The argument is not persuasive, because claim 39 recites specific amino acid position(s) such as His 470 without reference to an amino acid sequence, thus it is not clear which amino acid sequence is mutated at position 470.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 42 and 43 under USC 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, first and second paragraphs.

Continuation of 10. Other: The objection to the oath/declaration is withdrawn in view of applicants' response at page 12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
September 20, 2003